



NOTIFICATION PURSUANT TO 21 CFR 101.93  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Harmony Formulas, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Candistroyer Formula**, part of the 2-part Candida program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Clinically formulated to facilitate the elimination of Candida albicans.
- Statement 2. Binds to the bad bacteria and fungus in your body rendering them ineffective.
- Statement 3. Contains herbs that stoke the body's natural digestive fires.
- Statement 4. Supports immune function by increasing the blood supply to the spleen.
- Statement 5. Helps with digestive discomfort

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Zinc Tannates, barberry Root Extract, Golden Seal Root, Oregon Grape Root, Cinnamon Bark, Cloves, Pau D' Arco, Ginger Root & Thyme Leaf.
2	Zinc Tannates
3	Cinnamon Bark
4	Oregon Grape Root
5	Peppermint Oil, Orange Peel, Cloves

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Harmony Formulas® Candistroyer Formula	Labeling
2	Harmony Formulas® Candistroyer Formula	Both
3	Harmony Formulas® Candistroyer Formula	Both
4	Harmony Formulas® Candistroyer Formula	Labeling
5	Harmony Formulas® Candistroyer Formula	Labeling

I, R. Lindsey Duncan, am authorized to certify this Notification on behalf of 4Health, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that 4Health, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: June 30, 1998

By: [Signature]  
Dr. R. Lindsey Duncan CN, ND  
CEO and Formulator, 4Health, Inc.

97S - 0162

see docket 97S-0163 also

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LET 1906  
HF30171 05-29-98